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75	90 02/14/2005		EXAMINER	
Ginger R. Dreger			FREDMAN, JEFFREY NORMAN	
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Suite 1150			ART UNIT	PAPER NUMBER
201 California Street			1637	
San Francisco, CA 94111			DATE MAILED: 02/14/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/033,244	BOTSTEIN ET AL.	BOTSTEIN ET AL.			
		Examiner	Art Unit				
		Jeffrey Fredman	1637				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
THE I - External after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we re to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	66(a). In no event, however, may a within the statutory minimum of th ill apply and will expire SIX (6) MO cause the application to become A	reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this cor BANDONED (35 U.S.C.§ 133).				
1)🖂	Responsive to communication(s) filed on 27 L	<u> December 2004</u> .					
2a)⊠	This action is FINAL . 2b)☐ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
· _	on of Claims						
-	Claim(s) 22-27 is/are pending in the applicatio						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
·							
	Claim(s) <u>22-27</u> is/are rejected.						
_	Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1.☐ Certified copies of the priority documents have been received.							
	Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* S	See the attached detailed Office action for a list of						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to⁻a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s Informal Patent Application (PTO				

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 27, 2004 has been entered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 22-27 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a genus of antibodies which bind to a protein termed PRO1800 in the specification.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the proteins.

The cited utilities in the specification are that the protein is related to the Hep27 protein, which the specification states may be involved in some DNA synthesis related pathway.

There is some evidence of overexpression in certain lung tumors (but not in others) at page 117. These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the protein. No well established utilities for this specific PRO1800 protein, antibody or nucleic acid are identified in either the specification or in the cited prior art.

Substantial utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, the evidence in the specification provided is that the protein is related by homology to the Hep 27 protein. This relationship lacks any of the hallmarks of utility. The homology does not imply that the proteins are similar in any function way, or that they are expressed in similar tissue types or under similar conditions. There is no biological activity, expression pattern, phenotype, disease or condition, ligand, binding partner or any other specific feature which is disclosed as being associated with PRO1800. Without any further information, there is no expectation that the protein will have any properties in common with the Hep 27 protein. There is an abundance of evidence that very similar proteins can perform very different functions. For example, Rost et al (J. Mol. Biol. (2002) 318(2):595-608) notes regarding assignment of enzymatic activity based upon homology comparisons that "The results illustrated how difficult it is to assess the conservation of protein function and to guarantee error-free genome annotations, in general: sets with millions of pair comparisons might not suffice to arrive at statistically significant conclusions

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(abstract)." Thus, even high levels of homology do not necessarily correlate with actual protein function. In the current case, where not only is the function of PRO1800 not known, but no specific function has been definitively identified for the related Hep 27 protein itself, the expectation is even lower that there is any utility that can be derived based upon this association.

As noted in the utility guidelines, basic research on a product to identify properties and intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). First, there is NO data in the specification showing association of PRO1800 with any disease state.

Second, the overexpression data does not provide a substantial utility for several reasons. First, there is no showing that the overexpression was statistically significant and correlated with any diagnostic utility. The absence of such a diagnostic utility is particularly striking since there is no evidence that the overexpression effect was statistically significant, that the effect was reproducible, or that the effect was anything other than a nonspecific effect due to the presence of an exogenous protein in the mixture. Finally, the claims at issue are drawn to antibodies. In the current case, there is no evidence that the protein is expressed in any particular tissue type. There is no evidence that the protein is overexpressed in cancerous cells, or that the protein has any utility whatsoever. As numerous references show, there is no necessary relationship between nucleic acid expression in a cell and protein expression. For example, Pennica et al (Proc. Natl. Acad. Sci. (1998) 95:14717-14722) shows that the Wisp-2 DNA was amplified by the RNA expression was reduced in tumors (see

abstract). Konopka (Proc. Natl. Acad. Sci. (1986) 83:4049-4052) states that "Protein expression is not related to amplification of the abl gene but to variation in the level of bcr-abl mRNA produced from a single Ph1 template. (see abstract)." So even if there is a gene amplification, that would provide no utility whatsoever for the protein or antibody, since the gene amplification does not necessarily relate to the expression information of the protein and cognate antibody.

Third, the art supports the conclusion that many genes are irrelevant in gene microarray assays. As Li et al (J. Theoretical Biology (2002) 219:513-551) note "The presence of this power law function prevents an intrinsic cutoff point between "important" genes and "irrelevant" genes (see abstract)." Li continues in the text to note that "In a typical microarray experiment, however, the problem is not that one does not put enough genes on a chip, but rather having too many genes (see page 539, column 1)." This concept that genes whose expression does not change is irrelevant is not limited to Li. Ding et al (Bioinformatics (2003) 19(10):1259-66) notes "A two-way ordering of gene expression data can force irrelevant genes toward the middle in the ordering and can thus be discarded (See abstract)." So Ding expressly indicates that genes without change in expression profiling (and Ding's preferred embodiment is cancer genes) should be discarded. Ding notes at page 1259 that in a selection from thousands of genes, 50 are sufficient. Similarly, Sawiris et al (Cancer Research (2002) 62:2923-2928) notes "One of the advantages of specialized arrays is that they do not include irrelevant genes that may contribute to noise during data analysis (see page 2923, column 2)." Thus, the overwhelming state of the art supports the position that

many genes are irrelevant, that genes whose expression does not change are noise, and that these irrelevant genes are so insignificant that ideally they are not placed on the arrays or used at all. Therefore, such genes lack substantial utility as useful on gene expression arrays.

Specific Utility

In the current case, even if the substantial utility argument above were found unpersuasive, there is no specific utility given for this protein and resultant nucleic acid. The protein has not been associated with any disease, any condition, any enzymatic activity or any other specific feature. The only association is that it has some homology to a protein, Hep 27, which is associated with DNA synthesis in some undefined way. As the utility guideline training materials note on page 5-6, "Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed". Here, there is no disclosure of any condition which can be diagnosed and hence, no specific utility.

Finally, with regard to the utility analysis, the current situation directly tracks

Example 4 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility.

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Claim Rejections - 35 USC § 112 – Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to antibodies which bind the PRO1800 protein. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims broadly encompass any antibody which binds to the PRO1800 protein and also include any antibody fragments which bind to the PRO1800 protein.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant variability in the activity of polypeptides and antibodies. It would require significant study to identify the actual function of the PRO1800 protein, and identifying a use for this protein would be an inventive, unpredictable and difficult undertaking in itself. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is extremely unpredictable with regard to protein function in the absence of reliable information regarding the protein activity. Even very similar proteins, as shown by homology, may have very different functions (see Rost et al (J. Mol. Biol. (2002) 318(2):595-608). In the current case, where no specific information is known regarding the function of the protein in actual biological organisms, it is entirely unpredictable what function and activity will be found for this protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the protein.

Further, the art supports the conclusion that many genes are irrelevant in gene microarray assays. As Li et al (J. Theoretical Biology (2002) 219:513-551) note "The

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presence of this power law function prevents an intrinsic cutoff point between "important" genes and "irrelevant" genes (see abstract)." Li continues in the text to note that "In a typical microarray experiment, however, the problem is not that one does not put enough genes on a chip, but rather having too many genes (see page 539, column 1)." This concept that genes whose expression does not change is irrelevant is not limited to Li. Ding et al (Bioinformatics (2003) 19(10):1259-66) notes "A two-way ordering of gene expression data can force irrelevant genes toward the middle in the ordering and can thus be discarded (See abstract)." So Ding expressly indicates that genes without change in expression profiling (and Ding's preferred embodiment is cancer genes) should be discarded. Ding notes at page 1259 that in a selection from thousands of genes, 50 are sufficient. Similarly, Sawiris et al (Cancer Research (2002) 62:2923-2928) notes "One of the advantages of specialized arrays is that they do not include irrelevant genes that may contribute to noise during data analysis (see page 2923, column 2)." Thus, the overwhelming state of the art supports the position that many genes are irrelevant, that genes whose expression does not change are noise, and that these irrelevant genes are so insignificant that ideally they are not placed on the arrays or used at all. Therefore, such genes lack substantial utility as useful on gene expression arrays.

Finally, the claims at issue are drawn to antibodies. In the current case, there is no evidence that the protein is expressed in any particular tissue type. There is no evidence that the protein is overexpressed in cancerous cells, or that the protein has any utility whatsoever. As numerous references show, there is no necessary

relationship between nucleic acid expression in a cell and protein expression. For example, Pennica et al (Proc. Natl. Acad. Sci. (1998) 95:14717-14722) shows that the Wisp-2 DNA was amplified by the RNA expression was reduced in tumors (see abstract). Konopka (Proc. Natl. Acad. Sci. (1986) 83:4049-4052) states that "Protein expression is not related to amplification of the abl gene but to variation in the level of bcr-abl mRNA produced from a single Ph1 template. (see abstract)." So even if there is a gene amplification, that would provide no utility whatsoever for the antibody, since the gene amplification does not necessarily relate to the expression information of the antibody.

Working Examples

The specification has one working example in which the nucleic acid may be overexpressed in some tumor samples, but the working example was lacks sufficient information regarding internal controls to show that the protein was, in fact, overexpressed, that the nucleic acid was associated with any disease or that the results are anything other than spurious.

Guidance in the Specification.

The specification, while correlating PRO1800 with Hep 27, did not teach any actual function or use for PRO1800, nor, in fact, any use for Hep 27 itself.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the efficacy of the control and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

6. Applicant's arguments filed December 27, 2004 have been fully considered but they are not persuasive.

Applicant argues a set of case law distinct from Brenner v. Manson. This caselaw argument is not persuasive for several reasons.

Fundamental Utility Caselaw as applied to PRO1800

First, as discussed previously, in analyzing utility, the first place to begin is with the decision of the Supreme Court in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). In Brenner, the Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

There is no specific benefit, in currently available form, for the Pro-1800 protein and antibody, since there are no specific and substantial utilities for that Pro-1800 protein and antibody.

The CCPA first applied Brenner in In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51. The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are-or are not-in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53. The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly

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rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at

55.

The current situation is identical to that in Kirk. The Declarations filed provide evidence that one could determine whether the Pro-1800 protein is useful, but do not even show any utility specifically for Pro-1800 as discussed above. Further, the discussion cited by Applicant of the various declarations, such as the discussion on page 16 of the response, clearly represent language which is "useful in research" but has no current practical use. The speculation by the Declarants that medical practitioners might wish to know if proteins in general are overexpressed, without reference to Pro-1800 in particular, is precisely the sort of vague argument which lacks any specificity.

There is no particular therapy associated with overexpression of the Pro-1800 protein. There is no particular diagnosis associated with overexpression of the Pro-1800 protein. There is no particular use whatsoever associated with overexpression of the Pro-1800 protein and resultant antibody. There are only vague general statements that such an overexpression might be useful in research or therapy. This is insufficient according the to the Kirk court. This is particularly demonstrated when Applicant argues that the proteins might be useful for tissue typing (see page 17). This is a classic throwaway utility since there is no evidence that Pro-1800 protein is associated with any particular tissue at all.

Similarly, with regard to specific utility, the declaration, the arguments and the specification are entirely silent on any real specific utility for Pro-1800. When Applicant

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states that evidence of overexpression of PRO1800 nucleic acids provides utility to the protein, this presumes the protein is similarly overexpressed. As discussed at length above, this is not necessarily the case. Consequently, this cannot serve as a foundation stone to support specific utility.

Applicants cited caselaw

Applicant first cites Fujikawa v. Wattanasin for the proposition that utility need be shown only to a "reasonable certainty" and absolute proof is not required. This argument is not persuasive for two reasons. First, as evidenced by the art such as Pennica and Konopka, even if the the "reasonable probability" standard is used, there is no reasonable certainty that a protein will be overexpressed when the nucleic acid is expressed.

Second, and perhaps more importantly, the case is really inapposite to the current situation because the utility question is significantly different. In Fujikawa v. Wattanasin, the question was whether in vitro testing that showed a compound lowered cholesterol provided utility for that compound as confirmed by in vivo testing. In the current case, no in vivo results whatsoever are present. The use of the Fujikawa compound is expressly evident from the results, that is, the compound can be used to treat high cholesterol, and that is the use intended by that applicant. That situation is significantly different from the current case because there is no evidence that the Pro-1800 protein is diagnostic of cancer. Unlike the in vitro testing in Fujikawa v. Wattanasin, where a positive result provided an indication that the compound was potentially useful in cholesterol lowering, and which result was confirmed by in vivo

testing, a positive result of overexpression in lung cancer for the Pro-1800 nucleic acid provides very little information for utility of the nucleic acid. There is no "reasonable probability" that the nucleic acid would be diagnostic of cancer in any way, and significantly less than a "reasonable probability" for the Pro-1800 protein for which no evidence of utility whatsoever is presented. Antibodies to the Pro-1800 protein, which protein has not been shown to be overexpressed in cancer or to have any other use, lack any "reasonable probability" of utility. Consequently, the fact pattern of Fujikawa v. Wattanasin does not apply because the level of certainty in this case is below the "reasonable probability" required by that CAFC in that decision.

This is similar to the cited Cross v. lizuka case where specific inhibition of thromboxane synthetase was demonstrated for utility of the compounds. This is worlds apart from the current situation where no result whatsoever is shown for the claimed antibodies to Pro-1800. No therapeutic or functional utility is even alleged other than the concept that the antibodies may detect the Pro-1800 protein, for which no evidence of any utility has been provided. The closest asserted utility is for the Pro-1800 nucleic acid, and this utility, for the reasons extensively discussed in the rejection, above and previously, does not carry over into the protein.

The conclusion that is reached is that it is NOT more likely than not that there is a "reasonable probability" that the asserted utility for the antibodies is true.

Nonspecific Arguments

Applicant then cites a series of sources for the entirely nonspecific argument that for some proteins, nucleic acid overexpression is correlated with protein

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overexpression. As noted in the rejection, there are other articles which demonstrate that there is no necessary relationship for every protein. Nonspecific arguments do not relate to PRO-1800. None of the references demonstrate that there is a "reasonable probability" that the Pro-1800 protein is overexpressed or that antibodies to the Pro-1800 protein itself have any utility.

It is interesting that Applicant relies upon two cases, Fujikawa v. Wattanasin and Cross v. Iizuka, where specific evidence of utility for the specific molecules was presented, but Applicant fails to provide such evidence for Pro-1800 and attempts instead to rely upon other, unrelated proteins. Fujikawa v. Wattanasin and Cross v. Iizuka both seem to stand for the proposition that is consonant with Brenner v. Manson, which is that specific evidence of utility for the specific molecule claimed is required. That specific evidence is absent and the conclusion is inescapable that the antibodies to Pro-1800 therefore lack utility and this conclusion is maintained.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman

JEFFREY FREDMAN PRIMARY EXAMINER